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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/660,022 09/12/00 CABRERA A U-012473-1

HM12/0725

EXAMINER

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WARE, T

| ART UNIT | PAPER NUMBER |
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1615

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DATE MAILED: 07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                             |                        |                     |
|-----------------------------|------------------------|---------------------|
| <b>Offic Action Summary</b> | <b>Application N .</b> | <b>Applicant(s)</b> |
|                             | 09/660,022             | CABRERA ET AL.      |
|                             | <b>Examiner</b>        | <b>Art Unit</b>     |
|                             | Todd D Ware            | 1615                |

-- Th MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 19 January 2001 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-24 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6)  Other: \_\_\_\_ .

**DETAILED ACTION**

Receipt of declaration filed 1-19-01 and information disclosure statement filed 10-5-00 is acknowledged.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the limitation "intermediate layer (c)" in line 13. There is insufficient antecedent basis for this limitation in the claim. Is the "inert, non-alkaline coating" "intermediate layer (c)" or "layer (b)" or is the "system of modified release" "intermediate layer (c)" or "layer (b)"? This applies to paragraph four, as well.
4. Claim 1 recites the limitation "layer (b)" in line 13. There is insufficient antecedent basis for this limitation in the claim. Please see paragraph 3.
5. It is unclear whether the "inert, non-alkaline coating" or the "system of modified release" is one or two layers. If these are in one layer, then "non-alkaline polymer soluble in water" is repeated and renders the claim indefinite.
6. It is unclear how applicants consider the water-insoluble polymer as "non-alkaline." The examiner understands the pH of polymers as determined by their dissociation in an aqueous solution. However, these polymers are water-insoluble.

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Furthermore, these polymers do not appear to "accept protons" as in the Brönsted-Lowry concept of acids and bases or to donate an electron pair as in the Lewis Acid-Base model of acids and bases. Clarification is requested.

7. For purposes of examination, the claim is understood to recite: a) an inert nucleus, b) a layer of acid labile benzimidazole compound and non-alkaline, water-soluble polymer, c) a layer comprising non-alkaline, water-soluble polymer and non-alkaline, water-insoluble polymer (for purposes of examination, ethylcellulose or ammonium methacrylate, d) an enteric coating.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-21 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124).

'124 discloses pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-

C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC.

10. Claims 1-21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 and '856 disclose pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims).

#### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 teaches pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC. Plasticizers and other excipients are also

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contemplated. Furthermore, varying the thickness (therefore the amount) controls the release rate. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide mixtures of pellets having different release profiles in an effort to provide quicker release of the active agent while also providing prolonged release of the active agent.

13. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) in view of Paradissis et al (5,445,829; hereafter '829) or Sachs et al (6,068,856; hereafter '856) in view of Paradissis et al (5,445,829; hereafter '829).

'124 and '856 are relied upon for all that they teach as stated previously. Neither '124 nor '856 teaches the limitation where the pellets have different release profiles of the active agents.

'829 is relied upon for teaching capsules comprising fast and slow release layered pellets to provide both a quicker onset of action and a prolonged duration of action.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '829 with '124 or '856 with the expectation of providing a particular dose release profile that provides both a quick onset of action and a prolonged duration of action.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  


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July 20, 2001